PDUFA II
Five-Year Plan

FY 1999 Revision

1998 - 1999 - 2000 - 2001 - 2002

Department of Health and Human Services
FOOD AND DRUG ADMINISTRATION
Office of Management and Systems

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Executive Summary

The Prescription Drug User Fee Act of 1992 (PDUFA I) provided substantial additional resources and staffing that enabled FDA to accelerate its drug evaluation process without compromising review quality. The Food and Drug Administration Modernization Act (FDAMA) of 1997 amended PDUFA I and extended it through September 30, 2002 (PDUFA II). PDUFA II also commits FDA to faster review goals for some applications, new goals for meetings and dispute resolution, and the electronic receipt and review of applications by 2002.

In July 1998, FDA completed the original PDUFA II Five-Year Plan, which was FDA's blueprint for investing the resources expected under PDUFA II. It was based on the planning efforts of the three FDA components directly responsible for meeting these goals: (1) the Center for Drug Evaluation and Research (CDER), (2) the Center for Biologics Evaluation and Research (CBER), and (3) the Office of Regulatory Affairs (ORA). This is the first annual revision of that plan. The major changes from the original plan are summarized below:

- Assumptions have been significantly revised, based on a more conservative projection of PDUFA fee revenue. The estimate of revenue expected over the 5 years is reduced from $740 million to $681 million (a reduction of $59 million). This new revenue estimate is based on the regression analysis used to set FY 1999.
- CDER's revised plan calls for:
    - an increase of only 101 FTE's by the end of 5 years (scaled back from an increase of 240 FTE's in the original plan), with costs for additional staff and operating support to enhance the review process over the 5 years reduced from $103 million to $80 million, and
    - IT expenditures over the 5 years reduced from $61 million to $54 million.
- CBER's revised plan calls for:
    - a net increase of only 37 FTE's by the end of 5 years (scaled back from an increase if 57 additional FTE's in the original plan), with costs for additional staff and operating support to enhance the review process over the 5 years reduced from $25 million to $18 million; and
    - IT expenditures over the 5 years reduced from $34 million to $30 million.
- ORA's revised plan calls for:
    - a reduction of 40 FTE's over the 5 years (rather than an increase of 28 FTE's in the original plan), with costs for additional staff and operating support over 5 years reduced by $17 million (largely a result of increasing reliance on record reviews in lieu of on-site pre-approval inspections); and
    - IT expenditures over 5 years remain the same in both plans--$3 million.

Of the total planned, 56 percent will go for pay and benefits—down slightly from 58 percent originally planned. This will fund 98 more FTE's for the drug review process than were actually expended in 1997 (compared with 325 more in the original plan), or 757 more FTE's for the drug review process than were actually expended in 1992 (compared with 983 more in the original plan). Resource constraints may make meeting PDUFA triggers and goals more difficult in out-years.

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Purpose

This plan sets out, in broad terms, the five-year blueprint for investing the substantial resources FDA expects to collect under the Prescription Drug User Fee Act (PDUFA), as amended and extended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA must ensure that these resources are used to meet challenging new goals associated with PDUFA. The plan will help ensure that resources are used to achieve these goals. It allocates the resources expected each year among the FDA components responsible for achieving PDUFA goals.

The plan was originally developed in Fiscal Year (FY) 1998 and made available in July 1998. Annual reviews will be conducted and adjustments made as actual changes in workload and revenues replace original estimates, unanticipated contingencies occur, and new technologies develop. This FY 1999 revision of the plan is the first update of the original plan.

Background

PDUFA I

The Prescription Drug User Fee Act of 1992 provided FDA with increasing levels of resources for the review of human drug applications. Fees that FDA collected from drug and biologic firms, 1993 through 1997, were used to reduce the evaluation time for certain human drug applications without compromising review quality. Letters from the Commissioner of Food and Drugs to Congressional Committee Chairmen detailed these goals**.** By 1997, these fees were providing FDA with an additional $87.5 million a year to devote to the drug evaluation process.

FDA primarily spent these new resources to acquire personnel to review human drug applications and to update the information technology (IT) infrastructure supporting the human drug review process. FDA staff dedicated to these reviews in the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) increased over 57 percent during this period--from 1,147 staff-years in 1992 before PDUFA was enacted to 1,806 staff-years by 1997. FDA has submitted annual Performance and Financial Reports to Congress on progress in meeting performance goals and the use of fees.

The growing recognition of FDA's success in ensuring that these resources were well used culminated in late 1997 when FDA received the prestigious Innovations in American Government Award, jointly sponsored by the Ford Foundation and the Harvard University John F. Kennedy School of Government, in partnership with the Council for Excellence in Government. This award honored FDA's achievement in combining user fees and management principles to develop a new drug approval process that is predictable, accountable, and scientifically sound while making safe and effective drugs available to the public more quickly.

PDUFA contained a "sunset" provision for automatic expiration on September 30, 1997. Without further legislation, FDA would have been unable to continue to collect and spend PDUFA fees essential to maintain the review process improvements after that date.

PDUFA II

Congress worked with the regulated industry and the Administration to ensure PDUFA's continuation. As a result, the FDAMA was signed by President Clinton on November 21, 1997. Subtitle A of Title 1 of FDAMA amended PDUFA and extended it through September 30, 2002. This extension authorizes funds that will enable FDA to accomplish increasingly challenging goals over this five-year span. These new goals were set forth in letters from the Secretary of Health and Human Services to Congressional Committee Chairmen on November 12, 1997. PDUFA, as amended and extended by FDAMA and with its new goals, is referred to as PDUFA II and its predecessor is now referred to as PDUFA I.

PDUFA II authorizes appropriations that will provide FDA with resources to sustain the larger

drug review staff developed in the last 5 years and to achieve the even more stringent new goals.

New Goals

The new goals of PDUFA II are enormously challenging, diverse, and resource intensive. Major components of the review process will be accelerated further. Many of the goals will require the development and issuance of guidance documents and data bases to track and report performance. Goals are established in totally new areas, such as meetings with industry and dispute resolution. The development of infrastructure and tools necessary to move to electronic application receipt and review will also be essential. The following table provides an overview and comparison of the major goals by the end of PDUFA I and the end of PDUFA II. (For more detail on the actual goals and FDA's performance, see FDA's latest Performance Report submitted to Congress in December 1998.)

Comparison of Goals at the End of PDUFA I and PDUFA II

Goal	PDUFA I	PDUFA II
Complete review of priority original new drug applications and efficacy supplements	90% in 6 months	90% in 6 months
Complete review of standard original new drug applications and efficacy supplements	90% in 12 months	90% in 10 months
Complete review of manufacturing supplements	90% in 6 months	90% in 4 months if prior approval needed
Complete review of resubmitted new drug applications	90% in 6 months	90% of class 1 in 2 months and 90% of class 2 in 6 months
Respond to industry requests for meetings	No Goal	90% within 14 days
Meet with industry within set times	No Goal	90% within 30, 60, or 75 days, depending on type of meeting
Provide industry with meeting minutes	No Goal	90% within 30 days
Communicate results of review of complete industry responses to FDA clinical holds	No Goal	90% within 30 days
Resolve major disputes appealed by industry	No Goal	90% within 30 days
Complete review of special protocols	No Goal	90% within 45 days
Electronic application receipt and review	No Goal	In place by 2002

FY 1999 Revision

When the PDUFA II Five-Year Plan was originally published in July 1998, FDA committed to annual reviews and adjustments as actual changes in workload and revenues replace original estimates, unanticipated contingencies occur, and new technologies develop. This FY 1999 revision is the first update since the original plan was developed and published. Four of the assumptions in the next section have changed significantly in this revised plan as a result of our experience through the end of FY 1998, and annual revenue forecasts and expenditure plans are reduced.

One of the new features included in PDUFA II was a workload adjuster. Its purpose was to assure that fee revenues would increase proportionally with increases in workload. Likewise, when workload decreased, revenues would decrease. FDAMA made the number of fee-paying applications the surrogate for PDUFA workload.

In FY 1998, the number of applications submitted to FDA for review declined for the first time in 6 years, as noted in both the FY 1998 PDUFA Performance Report released in December 1998 and in the FY 1998 PDUFA Financial Report released in February 1999. FDAMA amendments exacerbated this decline, causing over 30 more applications to be exempt from fees than would have been exempt previously. Thus, there was a substantial decline in the number of fee-paying applications in FY 1998.

Total PDUFA workload, which includes the increasing volume of items exempt from fees as well as an increasing volume of work not subject to fees--such as investigational new drug submissions and manufacturing supplements--increased in FY 1998. Unfortunately, the PDUFA II workload adjuster does not reflect real changes in PDUFA workload.

FDA published a *Federal Register* notice on December 22, 1998, stating the number of fee-paying submissions received in FY 1998, and explaining that the past approach to estimating fee-paying applications for FY 1999 (based on the actual number received in the immediately preceding year) would be problematic. In that notice, FDA used linear regression analysis to estimate the number of fee-paying applications and application fee revenues for FY 1999. The notice also set product and establishment fees based on this forecast. Using that same method to estimate fee-paying applications and revenues through FY 2002, this plan revision significantly lowers the forecast of fee revenues through 2002, and expenditure plans are similarly scaled back.

Assumptions

Taking advantage of experience gained during PDUFA I and experience through FY 1998, this revised plan is based on ten major assumptions. Each of the assumptions was reassessed for FY 1999. Most are unchanged or have very minor revisions. However, assumptions 2, 4, 8, and 9 have been significantly revised, based on a more conservative projection of fee revenues. A discussion of all ten assumptions follows.

1. As in the original plan, the increases funded by PDUFA I will be maintained over the course of PDUFA II.

The fees collected during PDUFA I funded activities that became an integral part of FDA's resources for reviewing human drug applications. In 1997, two-thirds of these funds were spent on pay and benefits for an additional 659 Full Time Equivalents (FTE's) above the level of effort FDA was expending on the review of human drug and biologic applications in 1992. The remaining one-third of the funds was used to provide operating support, IT support, centrally funded support (for indirect costs such as utilities and telecommunications), rent, and overhead costs. The continuation of these 659 work-years of effort in the centers and ORA is crucial to FDA's ability to review drug and biologic applications rapidly. These resources are the foundation for building improvements mandated by PDUFA II.

PDUFA II ensures that these additional human resources (referred to as the PDUFA I additive base FTE's) continue to be dedicated to the drug review process over the next 5 years. They are allocated as follows:

PDUFA I Additive Base FTE's by Component

Year	CDER	CBER	ORA	Total
1998	398	187	74	659
1999 and Beyond	418	167	74	659

Adjustments in these allocations may be made if warranted by workload changes.

The 5-year estimated costs associated with these PDUFA I additive base activities are detailed in the table on the next page and reflect:

- Annual pay and benefit cost increases of 5 percent (based on 5 years' experience).
- Center support costs of $9,000 per FTE annually. These are base costs and exclude past allocations for specific projects or needs.
- ORA's support costs of $16,000 annually per FTE (largely due to ORA's travel costs for pre-approval inspections).
- Center support cost estimates also include research support funds for CBER of $590,000

in 1998 and $295,000 in 1999 (discontinued after 1999).

- Overhead calculated as a percent of center/ORA pay and benefits (a formula prescribed by the Office of the Assistant Secretary for Finance and found reasonable by Arthur Andersen, a major accounting firm, and validated by Inspector General audits).
- Central account and rent estimates are based on 1997 actual costs and inflated at 5 percent annually, based on experience over the past 5 years.

PDUFA I Additive Base Fund Estimates ($000)

Item	1998	1999	2000	2001	2002	*Total
Pay and Benefits for 659 Center/ORA FTE's	$61,366	$65,219	$68,480	$71,904	$75,499	**$342,469**
Center/ORA Support	$7,021	$6,726	$6,431	$6,431	$6,431	**$33,040**
Overhead	$10,889	$10,957	$11,505	$12,080	$12,684	**$58,114**
Central Accounts	$4,230	$4,642	$4,864	$5,097	$5,342	**$24,173**
***Total**	**$83,506**	**$87,544**	**$91,280**	**$95,512**	**$99,956**	**$457,797**

*Numbers may not add due to rounding.

2. Fee revenue estimates are based on annual increases of about 5 percent in fee-paying applications (rather than 7 percent as assumed in the original plan) and inflation increases of 3 percent. This revision reduces the estimated revenue over 5 years by over $62 million.

During discussions leading to the enactment of PDUFA II, both industry and FDA participants focused on the largely unanticipated increase in application review workload during PDUFA I and the need to ensure increasing revenues if this trend continues in PDUFA II. The following table, derived from the *Federal Register* Notices FDA published each year as a part of its fee-setting process, summarizes the increasing workload.

PDUFA Fee-Paying Full Application Equivalent Estimates by Year

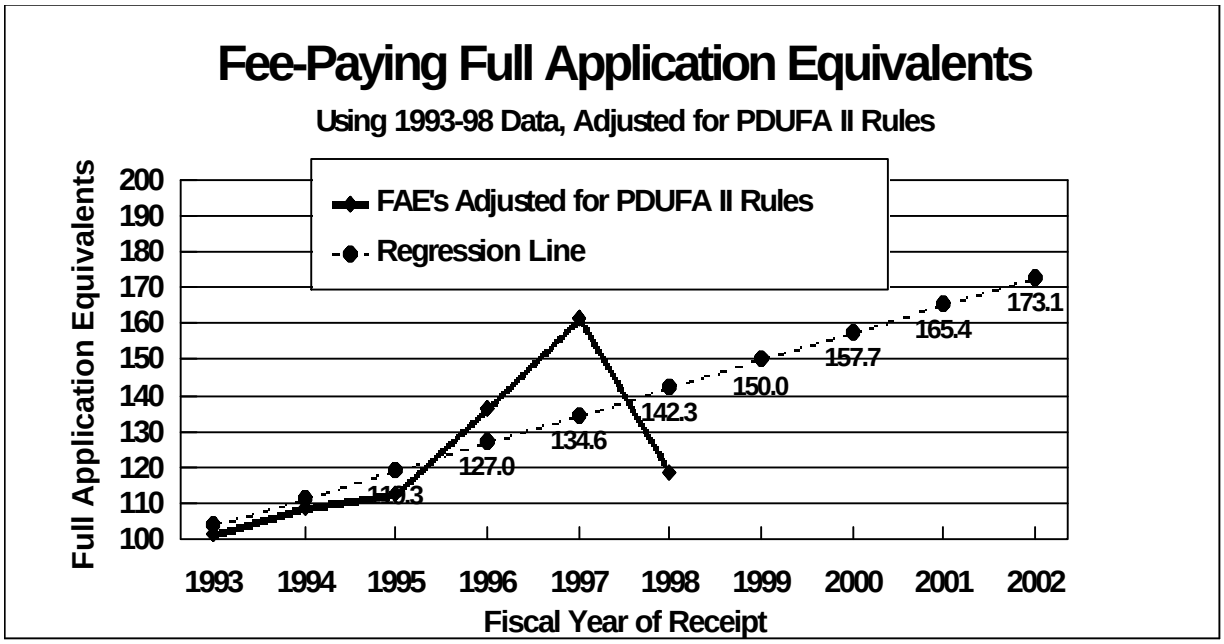
Fiscal Year	Full Application Equivalents	Percent Change from Previous Year	Allowance for Waivers or Reductions	Basis for Next Year's Fees	Percent Change from Previous Year
1993	116			116	
1994	129	11.2%	5	124	6.9%
1995	137	6.2%	6	131	5.6%
1996	157	14.6%	16	141	7.6%
1997	192	22.3%	40	152	7.8%

Based on this information (excluding 1997 data unavailable during discussions that led to PDUFA II) negotiators agreed that it was reasonable to include a workload adjustor in PDUFA II. The adjustor would cause FDA resources to increase or decrease as the workload fluctuated. The statute was crafted so that FDA fee revenues would increase in any year FDA anticipated receiving more than 142 fee-paying full application equivalents (the number used to set the fee level each year in the statute) and decrease in any year FDA anticipated receiving less than 142 fee-paying full application equivalents.

As part of these negotiations, FDA analyzed the effect of both increasing and decreasing workload levels and inflation. Industry and FDA negotiators agreed that the most reasonable planning scenario was a continued yearly increase in fee-paying application workload of 7 percent and inflation of 3 percent. These assumptions were the basis for projecting both revenues and workload in the original plan of July 1998.

In 1998, FDA received only 119 fee-paying full application equivalents, considerably below the 152 fee-paying full application equivalents estimated in the December 9, 1997 *Federal Register* notice. In light of this shortfall, the original projections above have been revised.

FDA published a *Federal Register* notice on December 22, 1998 (Attachment 1), using linear regression analysis to estimate the next year's number of fee paying applications and application fee revenues. Using that same method to estimate fee-paying applications and revenues through FY 2002 projects an increase of about 5 percent each year, as depicted in the graph below:



Based on the regression line shown above, FDA developed a projection of fee revenues that is included in Attachment 2. The following table summarizes the revised projection and how it differs from the original projection in July 1998.

Planned PDUFA Fee Collections by Year--Original, Now, and Difference ($000)

Item	1998	1999	2000	2001	2002	Total
Fees--Original Plan	$117,122	$132,273	$145,435	$167,168	$177,915	$739,913
Fees--Current Plan	$117,122	$122,527	$132,934	$149,273	$155,691	$677,547
Difference		($9,746)	($12,501)	($17,895)	($22,224)	($62,366)

As a result of this reassessment of potential revenues through FY 2002, this revised five-year plan assumes that revenue collections will be $62 million less than originally planned. The expenditures in this plan have been scaled back accordingly.

3. As in the original plan, each year FDA will spend approximately the same amount it collects in fees, maintaining an adequate carryover balance at the end of each year.

If FDA spends approximately as much as it collects each year, all of the PDUFA II revenues collected over the 5 years will be used. This assumption is possible because FDA began PDUFA II with a carryover balance--the PDUFA fees FDA collected but did not obligate by the end of the fiscal year and which are "carried over" for use in a future fiscal year. At the end of FY 1998, the carryover cash amounted to about $67.5 million. If FDA spends approximately the amount it collects each year, a similar carryover balance will continue at the end of each fiscal year. A carryover balance is necessary at the end of each year to ensure adequate operating funds in the first 4 months of each new fiscal year.

Each year, two-thirds of the PDUFA fees (product and establishment fees) are not paid to FDA until January 31--4 months after the fiscal year starts. The other one-third (application fees) is spread out over the year. For estimating purposes, this portion is distributed evenly over 12 months. These application fees in aggregate would cover FDA costs for 1⅓ months of the first 4 months of the fiscal year. FDA needs to carry forward at least 2⅔ months of operating costs into each new fiscal year to cover expenses until the product and establishment fees are received on January 31. In addition, because PDUFA contains provisions that could prevent FDA from being able to assess or collect fees (specified minimum levels that must be available from traditional appropriations), FDA has to maintain some reserves to cope with shut-down contingencies in any year. (Carryover balances are discussed further on pages 24-25.)

4. About $220 million will be available over 5 years for PDUFA II increases, rather than the $284 million estimated in the original plan.

If the total amount needed to sustain the PDUFA I initiatives derived under Assumption 1 is subtracted from the total revenues FDA expects to have available each year under Assumption 2, the net available for allocation to meet the PDUFA II goals is derived. Net available is the increment available to FDA over and above the PDUFA I additive base resources already invested

to support and maintain the 659 additional FTE's in the centers and ORA. This is the amount available for additional investments over the next 5 years to meet the PDUFA II goals.

Revenues Anticipated and Net Available for Allocation ($000)

Item	1998	1999	2000	2001	2002	Total
Fees Anticipated	$117,122	$122,527	$132,934	$149,273	$155,691	**$677,547**
PDUFA I Additive Base	$83,506	$87,544	$91,280	$95,512	$99,956	**$454,343**
Net Available	**$33,616**	**$34,983**	**$41,654**	**$53,761**	**$55,735**	**$219,750**

This represents about a 23 percent reduction from the amount planned in July 1998. Most of the reductions are achieved by reducing planned staffing levels. Information technology expenditures are are only slightly reduced, in order to achieve electronic receipt and review of applications by the end of FY 2002.

5. As in the original plan, all statutory conditions necessary for PDUFA to operate will be met each year.

The law allows FDA access to PDUFA II revenues only if three conditions are met. This plan assumes the following statutory conditions will be met:

- FDA appropriations (exclusive of user fees) in future years must total at least as much as FDA received in 1997, with some adjustments.
- Each year FDA must spend at least as much from appropriated funds (exclusive of user fees) on the human drug review process as it spent from appropriations (exclusive of user fees) on this process in 1997--with some adjustments.
- PDUFA fee revenues may be collected and spent only to the extent provided each year in FDA's appropriation.

6. As in the original plan, funds planned for acquiring human resources may be spent on either hiring or contracting.

To develop cost estimates, it was assumed that human resources would be acquired by hiring additional employees. The centers and ORA should not feel constrained in how necessary additional human resources are acquired. They are encouraged to utilize contract support any time it is more practical or cost effective than hiring.

7. As in the original plan, the amount FDA pays for rent for PDUFA and other programs will no longer be capped beginning in FY 1999.

For a substantial period before FY 1992, and continuing through FY 1998, FDA's Appropriation Act maintained a cap on the amount of rent FDA could pay the General Services Administration

(GSA). As a result, since there was no increase in rent costs from FY 1992 through FY 1998, PDUFA fees were not used to pay for GSA rent--the flat GSA rent payments were all a part of the PDUFA appropriated base.

The FY 1999 Appropriation Act for FDA no longer contains that cap and requires FDA to pay full GSA rent charges just as all other government departments and agencies do. With the removal of the cap, the total amount of rent that FDA will pay to GSA will almost double--increasing from $46.3 million in FY 1998 to $88.3 million in FY 1999. This will impact all programs, including the human drug review process. The share of rent payable for the human drug review process will increase by $5.4 million. This plan assumes that rent costs after FY 1999 will increase with inflation (3 percent annually).

Estimated Rental Payments for Human Drug Review Process ($000)

Rent Paid to GSA	1998	1999	2000	2001	2002
From Rent Appropriation	$6,466	$6,559	$6,704	$6,858	$7,016
From PDUFA Fees	$0	$5,428	$5,643	$5,859	$6,083
Total Rent Paid to GSA	**$6,466**	**$11,987**	**$12,347**	**$12,717**	**$13,099**

8. A small but increasing amount will be held in a contingency reserve each year after 1999--almost double the amount in the original plan.

The likelihood that unanticipated events will occur increases each succeeding year of the plan. To cope with these events, a small but increasing amount will be held in a contingency reserve each year after 1999. One such contingency is utility costs that FDA did not have to pay in 1997 and earlier but may have to pay in the future. However, these contingency reserves are being kept to a minimum in order to allocate as much of the planned revenue to the centers and ORA as possible to implement their plans. All funds anticipated during FY 1998 and FY 1999 are allocated in the plan.

Contingency reserves of $3 million, $4 million, and $7 million are planned for fiscal years 2000, 2001, and 2002, respectively. These contingency reserves have been almost doubled from the total in the original plan to help the agency cope with revenue uncertainty inherent in PDUFA II. Potential claims on this reserve will be assessed in the second quarter of each fiscal year and allocations will be made. Funds not required for contingencies will then be allocated among CDER, CBER, and ORA for PDUFA needs.

9. Over the course of PDUFA II, total funding from all sources for the human drug application review process should increase by about 36 percent, rather than by 45 percent as originally estimated.

The above assumptions permit a projection of revenues available for the review of human drug

applications through 2002--shown in the chart below. The revenues resulting from PDUFA II will allow program funding to increase by about 36 percent over the 5 years of this program--from $232 million in 1997 to $316 million in 2002. At first this may appear large. Average salary and benefit costs alone, which account for well over half of all costs, are expected to increase by about 28 percent by the end of 5 years--the compounded result of an average increase of 5 percent each year. This leaves a rather modest increase for other costs--particularly in light of the very intense investment in information technology required to achieve the PDUFA II goal of electronic receipt and review of applications by the end of FY 2002. Thus, this revised plan reflects substantially fewer additional employees than the original plan.

Viewed from another perspective, this increase is less than the compounded increase in workload (5 percent) and inflation (3 percent) that forms the basis of the revenue projections. Workload and inflation increases alone, when compounded, exceed 47 percent over 5 years. And inflation at 3 percent really understates the costs of inflation that FDA expects to experience, since pay and benefit increases have historically been at substantially higher levels (5 percent).

This PDUFA II 5-year plan revision is based on the total revenue stream shown in the table below.

Projection of Funds Available for the Human Drug Application Review Process ($000)

Source of Funds	1997 Actual	1998 Estimate	1999 Estimate	2000 Estimate	2001 Estimate	2002 Estimate
S&E Appropriations	$141,493	$141,493	$143,525	$146,682	$150,056	$153,507
Fees from Industry	$84,289	$117,122	$122,527	$132,934	$149,273	$155,691
Rent Appropriations	$6,466	$6,466	$6,559	$6,704	$6,858	$7,016
***Total Funds**	**$232,249**	**$265,081**	**$272,611**	**$286,320**	**$306,187**	**$316,214**

*Numbers may not add due to rounding. The S & E Appropriation amounts are projections of the minimum amounts that must be spent from appropriations on the process for the review of human drug applications in order to meet the statutory requirements of PDUFA II.

10. As originally planned, the plan will be reassessed and revised annually.

All allocations in the plan are subject to review and reassessment early in each fiscal year as figures for workload and revenue for the previous year are available and better estimates for the next year's revenues are made. Of course, adjustments will have to be made based on these assessments. The plan will continue to have value as the baseline from which future changes will be made. This annual reassessment process is discussed further on page 28.

Plans

The planning process for meeting new PDUFA II goals began during discussions with industry in the last year of PDUFA I. As new goals were proposed, resource implications were also estimated and discussed. These ongoing discussions over many months resulted in the PDUFA II goal letters of November 12, 1997 and the PDUFA II resource levels and adjustors to achieve those goals that were enacted in the statute.

The PDUFA II Five-Year Plan completed in July 1998 reflected the resources FDA initially anticipated and plans for investing those resources. Responding to the reduced resources FDA now anticipates, the Deputy Commissioner for Management and Systems issued scaled-back planning targets to CBER, CDER, and ORA in December 1998. The lowered planning targets were kept in proportion to the amount for each component in the original plan of July 1998. Each component was then asked to revise its plan, keeping within the new lowered targets and assuring that PDUFA II goals would be met.

The Office of Management and Systems (OMS) worked with CDER, CBER, and ORA to integrate their plans into an overall FDA plan. The primary focus of this effort was to ensure sound plans supporting PDUFA II goals. The IT portions of each component's plan is provided in more detail in the PDUFA II Information Management Five-Year Plan--Attachment 3. This revised IT plan presents more detail than last year's plan and better explains how IT projects support one another. It also identifies Electronic Regulatory Submission and Review (ERSR) accomplishments to date.

The overall PDUFA II Five-Year Plan revision resulting from this process provides a sound framework for the investments needed to ensure FDA success with PDUFA II. The following pages summarize the planned distribution of PDUFA II funds to each component (CDER, CBER, and ORA) over the next 4 years and an FDA Plan Summary. The two largest demands continue to be: (1) additional human resources to meet the more stringent application review times under PDUFA II goals and (2) IT investments to achieve paperless application receipt and review by the end of PDUFA II.

CDER Plan Summary

CDER has developed an amended, detailed overall plan for the 5 years of PDUFA II, reflecting the revised resource level estimates. The revised plan totals $133.3 million--a reduction of $30.1 million over the final 4 years of the program. A year-by-year resource summary of CDER's plan is on page 15. It has the same three principal components as last year's plan: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

The largest portion of CDER's initial plan was for funds to hire and support additional staff for the drug evaluation process. This represented $91.4 million (56 percent) of CDER's total plan and would have enabled CDER to add 240 more FTE's to the drug review process by FY 2002.

Confronted with the substantially reduced PDUFA revenues and continuing challenges of recruiting and retaining the highly skilled work force demanded for the medical and scientific evaluation of applications, CDER has substantially reduced the Personnel and Support component of its revised plan. This plan now reflects increasing Personnel and Support for CDER by $45.8 million (about 35 percent of planned resources), which will support 101 additional FTE's by FY 2002 (mostly in CDER's Office of Review Management). This number is in addition to the PDUFA I additive base of 418 FTE's and CDER's appropriated PDUFA base of 749 FTE's--for a total PDUFA effort of 1268 FTE's by FY 2002.

Recognizing that it takes 12 to 24 months for new employees to become proficient reviewers, CDER will try to hire most of the new staff in fiscal years 1999 and 2000. This will allow staff to be trained and to handle the increased workload associated with PDUFA II goals and increasing workload during the final 2 years of PDUFA II.

The Personnel and Support subtotal also includes funds to acquire more space for this additional staff--$1.8 million over the 5 years. This amount will be used to pay increased rental costs to GSA and will be held in reserve until arrangements are made for acquisition of this additional space.

Review Process Enhancements

The second component of CDER's plan is funding for a number of enhancements to the application review process. This has increased substantially from CDER's initial plan. CDER plans $34 million (25 percent of the total plan) for this purpose through FY 2002. These improvements span many offices which directly contribute to or support the attainment of PDUFA II goals. It includes funds to: standardize and improve review practices, enhance medical library resources for reviewers, expedite the validation of methods in new drug applications, train reviewers, increase clinical trial inspections, and improve PDUFA time reporting systems, enhance support and services for the drug listing program, enhanced document management and accountability, and support for additional advisory committee meetings essential

to expedite review. Also included are estimated travel funds for International Conference on Harmonization (ICH) meetings that will promote accelerated drug development through agreements on shared standards for use in the United States, Japan, and European pharmaceutical authorities. The actual distribution of these funds will be decided each year by the Office of International and Constituent Relations which coordinates ICH activities.

Information Technology

The final component of CDER's plan is $53.6 million (40 percent of the total) for IT enhancements for the drug review process and includes three parts: (1) funds to develop the capability for electronic application receipt and review by FY 2002 which account for $20.7 million, (2) funds for replacing CDER's management information system which account for $9 million, and (3) funds for many other IT enhancements that support the PDUFA II goals (such as replacement of one-third of the personal computers of the reviewers every 3 years and overall maintenance and upgrading of CDER's data systems and networks that support PDUFA) which account for $18.5 million over 5 years. The CDER IT reserve also includes another $5.3 million that is tentative, pending further discussion with FDA's Office of the Chief Information Officer (OCIO).

The IT goals for PDUFA remain fixed and this part of CDER's plan has changed the least from last year.

The IT part of the plan was compared to industry practices and standards utilizing outside contract support. As a result, some adjustments were made and other amounts are held in reserve until more complete plans for their use are agreed to between CDER and the OCIO. The OCIO will advise CDER on how funds held in reserve can be released and any other clearance processes for planned funds for IT projects.

The table on the following page summarizes CDER's revised plans to invest the additional funds made available as a part of PDUFA II. The table at the bottom of the following page summarizes the total PDUFA funds added to CDER each year. The first three lines show the amounts to support the PDUFA I additive base funds. The fourth line shows the total PDUFA II plan request and the last line shows the total of the PDUFA fee revenues planned for CDER each year.

FY 1999 Five-Year Plan Revision

CDER Plan Summary Tables--PDUFA II

Plan for Funds in Addition to PDUFA I Additive Base ($000)

Note: Numbers Are Rounded and May Not Add

Category		1998	1999	2000	2001	2002	5-Year Total
PDUFA Additive FTE's Base		398	418	418	418	418	
PDUFA Additive FTE's in This Plan	(1)	421	479	509	519	519	
Additional FTE Requested (Cum)		23	61	91	101	101	
(Increment Each Year)		23	38	30	10		
Additional FTE Payroll	(2)	$1,954	$5,464	$8,559	$9,974	$10,473	$36,423
Operating Support for Additional FTE's	(3)	$207	$549	$819	$909	$909	$3,393
Startup Costs for New FTE (One-time)	(4)	$219	$361	$285	$95	$0	$960
Recruit/Relocation/Renos/Security		$1,221	$550	$500	$500	$500	$3,271
OMS Reserve for Additional Space			$305	$455	$505	$505	$1,770
Subtotal--Personnel and Support		**$3,600**	**$7,229**	**$10,618**	**$11,983**	**$12,387**	**$45,817**
ICH Support	(5)	$420	$365	$420	$420	$420	$2,045
Redesign of Sci. Review Process		$3,392	$8,144	$6,926	$6,739	$6,760	$31,961
Subtotal--Process Enhancements		**$3,812**	**$8,509**	**$7,346**	**$7,159**	**$7,180**	**$34,006**
Electronic Submissions		$4,979	$4,545	$4,846	$3,245	$3,115	$20,730
Document Management		$1,772	$2,966	$2,053	$1,134	$1,135	$9,060
Other Electronic Initiatives	(6)	$4,998	$4,488	$3,619	$2,685	$2,740	$18,530
Reserve Pending OIRM Approval	(7)	$939	$0	$2,050	$1,150	$1,150	$5,289
Subtotal--Information Technology		**$12,688**	**$11,999**	**$12,568**	**$8,214**	**$8,140**	**$53,609**
Total Plan--CDER		**$20,100**	**$27,737**	**$30,532**	**$27,356**	**$27,707**	**$133,432**

(1) PDUFA Additive FTE Base (preceeding line) plus Net Additional FTE included in this plan.
(2) Salary and benefits estimated at $85,228 in 1998 and escalated at 5% annually thereafter. The 1998 amount is reduced by 75% for a July 1 estimated on-board date.
(3) Operating Support per FTE is calculated at $9,000 per year.
(4) $9,500 per FTE is provided in first year only for start-up costs.
(5) Estimate only: Actual distribution of ICH funds will be decided each year by the Office of External Affairs.
(6) Includes $150,000 for enhancing eitherCDER or ORA automated system for tracking bioresearch monitoring inspections
(7) Funds in this line include potential upgrades for CDER systems. These reserves will be released after the FDA Chief Information Officer has approved their use.

Total Additive PDUFA Funds for CDER--Base and Plan ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
Base Payroll for 418 FTE's (5% Inflation) *	$40,517	$44,532	$46,758	$49,096	$51,551	$232,455
Base Operating Funds	$3,582	$3,762	$3,762	$3,762	$3,762	$18,630
Subtotal--Base Allottment	$44,099	$48,294	$50,520	$52,858	$55,313	$251,085
Total for PDUFA II Five-Year Plan	$20,100	$27,737	$30,532	$27,356	$27,707	$133,432
Total PDUFA Additive Funds--CDER	**$64,199**	**$76,031**	**$81,052**	**$80,215**	**$83,020**	**$384,517**

* Payroll Base is for 398 FTE's in 1998 and 418 Each Year Thereafter (20 FTE's Transferred from CBER)

CBER Plan Summary

CBER has developed an amended, detailed overall plan for the 5 years of PDUFA II, reflecting the revised resource level estimates. The revised plan totals $48.4 million--a reduction of $10.6 million over the final 4 years of the program. A year-by-year resource summary of CBER's plan is on page 18. It has the same three principal components as last year's plan: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

CBER had an unusually high personnel attrition rate in FY 1998. Because the PDUFA program is such an integral part of the center's activities, it caused CBER to underburn PDUFA FTE's for the first time. The unsettled nature of the FY 1999 PDUFA revenue forecast precipitated a hiring freeze early in the fiscal year for several months. This coupled with the large underburn from the previous fiscal year leads CBER to project an underburn of about 10 FTE's in FY 1999. This takes into account CBER's plan to hire an additional 15 FTE's during FY 1999, which will require operating support and start-up costs. This underburn will reduce the FY 1999 personnel and support costs by $1 million and effectively reduce the net increase for that fiscal year to 5 FTE's.

CBER's plan is to bring on board the FTE's indicated early in PDUFA II due to the changes in the PDUFA goals, the lead-time required for new personnel to become effective reviewers, and the added tasks necessary to review these applications. CBER has a large proportion of fee-exempt and fee-waived applications that still must meet the PDUFA goals. Hiring the majority of the FTE's in the early years will allow CBER to process these applications without extreme hardship. All of the CBER FTE numbers still reflect the reprogramming of the 39 PDUFA I additive base FTE's from research into review activities (13 each year for FY 1998, 1999, and 2000) because of the PDUFA II agreement to phase out funding research with fee revenues.

In FY 2000, the final 13 FTE's will be reprogrammed from research into review work. In the revised plan, additional FTE's for FY 2000 are reduced from 6 to 3. Because of the continued lower than projected user fee revenues, FY 2001 FTE additions were reduced from 11 additional to 3 and in FY 2002, no additional FTE's are anticipated. The majority of these cuts were taken in the area of priority application review, dispute resolution, and protocol assessment.

The total funds for CBER Personnel and Support include pay and benefits for the additional FTE's and operating costs to support them. In FY 1999, the funds for acquiring space to house the additional staff has been eliminated since attrition during the previous year made space available. The reduction of staffing in future years has reduced the amount of this item in the last 3 years of the program. CBER's total payroll has been revised to $14.4 million, 29.7 percent of the total request. It was previously 33 percent of the total.

Review Process Enhancements

CBER's reduction in the review process enhancements was more modest, and still remains 9 percent of the total plan. However, the Document Control Center funding was modified as was training due to the reduction in new hires and lower anticipated revenues. The ICH travel funds reflect projections based on FY 1998 actual amounts and the FY 1999 plan for funds. The actual distribution of these funds will be decided each year by the Office of International and Constituent Relations which coordinates ICH activities.

Information Technology

The Information Technology (IT) component was reduced by $4.5 million but remains the largest part of CBER's plan -- $ 29.9 million (62 percent of the total plan). The reduction in FTE's does not impact the necessity to develop and enhance the IT environment needed to meet PDUFA II goals. FY 1999 shows a slight increase in planned funds, and then a reduction in the remaining 3 years. Reductions in the IT categories of Electronic Submissions and Other Electronic Initiatives have been off-set by increases in the Document Management area.

The Electronic Submissions area will focus primarily on the establishment of CBER's Electronic Document Room. CBER will work closely with CDER on other aspects of electronic submissions (e.g., electronic signature, secure e-mail) to achieve the paperless submission environment by the end of FY 2002. For the Other Electronic Initiatives area, the decrease will result in a longer desktop replacement cycle and a more conservative network infrastructure upgrade approach.

The increase in the Document Management area will be directed toward two projects: (1) the Biologics Regulatory Management System (BRMS) and (2) the Regulatory Management System (RMS). The BRMS is CBER's existing application review management system. The RMS is the projected application review management system which will incorporate project management concepts. The RMS is an integral part of CBER's Managed Review Process. The development and implementation of RMS has been delayed. More resources are needed to add staff to the development effort. In addition, resources are required to enhance the legacy system, BRMS, until it is replaced by RMS.

The table on the following page summarizes CBER's revised plans to invest the additional funds made available under PDUFA II. The table at the bottom of the page summarizes the total PDUFA funds added to CBER each year. The first three lines show the amounts to support the PDUFA I additive base funds. The fourth line shows the total PDUFA II plan, and the last line shows the total of the PDUFA fee revenues planned for CBER each year.

CBER Plan Summary Tables--PDUFA II

Plan for Funds in Addition to PDUFA I Additive Base ($000)

Note: Numbers Are Rounded and May Not Add

Category		1998	1999	2000	2001	2002	5-Year Total
PDUFA Additive FTE's Base		187	167	167	167	167	
PDUFA Additive FTE's in this plan	(1)	203	198	201	204	204	
Total FTE's Needed to Meet PDUFA II Goals		29	57	73	76	76	
FTE's Reprogrammed from Research		-13	-26	-39	-39	-39	
Net Additional FTE Requested		**16**	**31**	**34**	**37**	**37**	
(Increment Each Year)		16	15	3	3	0	
Salary and Benefits for Additional FTE's	(2)	$309	$1,733	$2,945	$3,366	$3,534	$11,887
Operating Support for Additive FTE's	(3)	$144	$279	$306	$333	$333	$1,395
Start-up Costs for new FTE (One-time)	(4)	$152	$143	$29	$29	$0	$352
Moves and Renovations			$0	$75	$75	$0	$150
OMS Reserve for Additional Space				$170	$185	$185	$540
Subtotal--Personnel and Support		**$605**	**$2,154**	**$3,525**	**$3,987**	**$4,052**	**$14,323**
Review Process Improvements		$976	$1,037	$730	$575	$575	$3,893
ICH	(5)	$80	$46	$50	$50	$50	$276
Subtotal--Process Enhancements		**$1,056**	**$1,083**	**$780**	**$625**	**$625**	**$4,169**
Electronic Submissions		$1,453	$1,360	$668	$599	$599	$4,679
Document Management		$4,228	$4,737	$2,890	$2,805	$2,751	$17,411
Other Electronic Initiatives		$2,044	$1,928	$1,495	$1,132	$966	$7,565
Reserve Pending OIRM Approval	(6)	$225	$0	$0	$0	$0	$225
Subtotal--Information Technology		**$7,950**	**$8,025**	**$5,053**	**$4,536**	**$4,316**	**$29,880**
Total Plan--CBER		**$9,611**	**$11,262**	**$9,358**	**$9,148**	**$8,993**	**$48,372**

(1) PDUFA Additive FTE Base (preceeding line) plus Net Additional FTE Requested (bolded line below).
(2) Salary and benefits estimated at $82,505 in 1999 and escalated at 5% annually thereafter. The FY 1999 amount is reduced by 10 FTE, because of hiring late in the year.
(3) Operating Support per FTE is calculated at $9,000 per year.
(4) $9,500 per FTE is added only in first year for start-up costs (desk, PC, etc,).
(5) Estimate only: Actual distribution of ICH funds will be decided each year by the Office of External Affairs.
(6) Reserves will be released after FDA Chief Information Officer approves uses.

Total Additive PDUFA Funds for CBER--Base and Plan ($000)

Note: Numbers Are Rounded and May Not Add

Category		1998	1999	2000	2001	2002	5-Year Total
Base Payroll for 167 FTE's (5% Inflation)	*	$15,800	$15,320	$16,087	$16,891	$17,735	$81,833
Base Operating Funds	**	$2,273	$1,798	$1,503	$1,503	$1,503	$8,580
Subtotal--Base Allottment		$18,073	$17,118	$17,590	$18,394	$19,238	$90,413
Total New Request		$9,611	$11,262	$9,358	$9,148	$8,993	$48,372
Total PDUFA Additive Funds--CBER		**$27,684**	**$28,381**	**$26,947**	**$27,542**	**$28,231**	**$138,785**

* Payroll Base is for 187 FTE's in 1998 and 167 each year thereafter (20 FTE Transferred to CDER).
** Operating Base is reduced by $295,000 in 1999 and 2000 as PDUFA additive research is phased out.

ORA Plan Summary

ORA has developed an amended plan for the 5 years of PDUFA II, reflecting the revised resource level estimates. This plan represents a major revision of last year's plan, and reflects substantial reductions in ORA resources over the remaining 4 years of PDUFA II. The table at the top of page 21 presents a year-by-year resource summary of ORA's plan. It has the same three principal components as the center plans: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

ORA is experiencing a marked decline in its PDUFA workload--specifically in demand for pre-approval inspections. In FY 1999 the time reported for PDUFA activities in ORA's time reporting system is decreasing, and, based on this trend, even lower levels are predicted beyond FY 1999. This results in a decrease in the use of PDUFA resources because most of the field PDUFA reimbursement formula depends on time reported in the field information system. It is difficult to predict the precise amount of time that will be reported because both the reporting and use of field time is not a linear function of time. Both assignments and reporting ebb and flow during the year.

ORA has identified several trends that appear to have caused the decline in PDUFA work. Over the last 3 years an increasing number of PDUFA decisions were based on the ORA Profiles database on establishment inspections. CDER's Office of Compliance increasingly uses field data to make decisions in lieu of requesting pre-approval inspections. District offices are also able to make PDUFA recommendations to CDER using field records, decreasing the need for PDUFA inspections. The increase in use of alternatives to inspections is a real trend.

In response to these circumstances, ORA's plan calls for 10 fewer FTE's in FY 1999, and for 40 fewer FTE's in each subsequent year. This means that staffing for ORA will fall substantially below its PDUFA I additive base of 74, so the decline in resources is reflected in negative numbers in the table on page 21. This reduction of 40 FTE's will mean that ORA will be expending a total of about 140 FTE's each year on PDUFA activities in the last year of the plan (34 FTE's paid from PDUFA fees and 106 FTE's paid from appropriations). In 2001 and 2002, as mutual recognition agreements with the European Union become effective, some of these resources will manage international agreements rather than conduct preapproval inspections.

Support costs are reduced for each FTE ORA looses in this plan revision. This reduction is $9,000 per year (rather than the $16,000 per ORA FTE added during PDUFA I). This lower reduction is based on the expectation of continuing and increasing international travel for preapproval inspections for remaining ORA personnel.

Review Process Enhancements

The second component of ORA's plan is $3.5 million for enhancements to support preapproval inspection work. These enhancements include equipment, training, and better time accounting. Inadequate laboratory equipment to analyze samples collected during pre-approval inspections has delayed field completion of some pre-approval inspection work. For PDUFA II, ORA plans $1.1 million over 5 years to purchase specific pieces of equipment required to analyze pre-approval inspection samples. ORA is also planning on $900,000 over 5 years for PDUFA-related training. ORA's training needs are exacerbated because the 164 staff-years devoted to PDUFA in FY 1999 represent time spent by about 600 different employees. Training and refresher courses for those who conduct PDUFA pre-approval inspections or analyze samples collected have to be provided to most of these 600 individuals who contribute to the 164 FTE's of PDUFA work. The amount requested for training will meet this need. ORA's process enhancement subtotal also includes $1.5 million to upgrade and improve its PDUFA time accounting system and to make it comparable to CDER and CBER systems. ORA's current system was designed over 25 years ago and needs to be updated.

Information Technology

The final component of ORA's plan is $3.3 million to enable the field offices to receive and review electronic applications to enable field staff to prepare for pre-approval inspections. The requested funds will allow ORA to develop and update its information management infrastructure to allow paperless application processing.

The table at the bottom of the following page summarizes the total PDUFA funds added to ORA each year. The first three lines show the amounts to support the PDUFA I additive base funds. The fourth line shows the total PDUFA II plan request, and the last line shows the total of the PDUFA fee revenues planned for ORA each year.

FY 1999 Five-Year Plan Revision

ORA Plan Summary Tables--PDUFA II

Plan for Funds in Addition to PDUFA I Additive Base ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
PDUFA Additive FTE Base	74	74	74	74	74	
PDUFA Additive FTE in this Plan (1)	74	64	34	34	34	
Additional FTE Requested	0	-10	-40	-40	-40	
(Increment Each Year)	0	-10	-30	0	0	
Additional FTE Payroll (2)	$0	($675)	($2,836)	($2,978)	($3,127)	($9,617)
Support Costs @ $9,000/FTE	$0	($90)	($360)	($360)	($360)	($1,170)
FTE Start-up Costs (3)	$0	$0	$0	$0	$0	$0
Subtotal--Personnel and Support	**$0**	**($765)**	**($3,196)**	**($3,338)**	**($3,487)**	**($10,787)**
Equipment	$230	$275	$189	$203	$218	$1,115
Training	$148	$270	$175	$140	$184	$917
FACTS Upgrade to Monitor & Track Time		$0	$400	$1,100	$0	$1,500
Subtotal--Process Enhancements	**$378**	**$545**	**$764**	**$1,443**	**$402**	**$3,532**
Electronic Submissions	$165	$80	$426	$501	$551	$1,723
Document Management		$0	$22	$11	$21	$54
Other Electronic Initiatives	$360	$0	$538	$261	$399	$1,558
Information Technology (4)	**$525**	**$80**	**$986**	**$773**	**$971**	**$3,335**
Total Plan--ORA	**$903**	**($140)**	**($1,446)**	**($1,122)**	**($2,114)**	**($3,920)**

(1) PDUFA Additive FTE Base (preceeding line) plus additional FTE's included in this plan.
(2) ORA pay and benefits based on 1999 estimate of $67,530 per FTE increasing at 5% annually.
(3) $9,500 per FTE is provided only in first year an FTE is added to cover one-time start-up costs.
(4) This line does not include $150,000 in CDER plan for enhancing either CDER or ORA automated tracking system for bioresearch monitoring inspections.

Total Additive PDUFA Funds for ORA--Base and Plan ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998	1999	2000	2001	2002	5-Year Total
Base Payroll for 74 FTE (5% Inflation)	$5,049	$5,367	$5,635	$5,917	$6,213	$28,181
Base Operating Funds (3% Inflation)	$1,166	$1,166	$1,166	$1,166	$1,166	$5,830
Subtotal--Base Allottment	$6,215	$6,533	$6,801	$7,083	$7,379	$34,011
Total New Request	$903	($140)	($1,446)	($1,122)	($2,114)	($3,920)
Total PDUFA Additive Funds--ORA	**$7,118**	**$6,393**	**$5,355**	**$5,961**	**$5,265**	**$30,092**

Overhead Summary

After the plans for CDER, CBER, and ORA were developed, the Office of Management and Systems estimated the overhead costs for PDUFA II and allocations of the overhead funds. This section provides background information on how overhead is calculated and used and summarizes plans for use in PDUFA II.

Overhead Calculation

As FDA developed PDUFA baseline costs in 1993, the Office of the Assistant Secretary for Finance prescribed the formula FDA uses to determine non-center headquarters (NCHQ) overhead costs. That formula conforms with generally accepted accounting principles and was found reasonable by Arthur Andersen consultants in subsequent annual audits. The formula is:

Total Costs of NCHQ ÷ (Salary Costs of All of FDA - NCHQ Salary Costs) = Overhead Rate

The salary costs used in this formula do not include any benefit costs. At the end of each fiscal year, the Office of Financial Management recalculates this overhead rate. To determine overhead costs attributable to the PDUFA activities, this rate is multiplied by the total PDUFA salary costs (excluding benefits) for CDER, CBER, and ORA. In 1998, FDA spent a total of $253.5 million on the drug review process as defined in PDUFA, and the 1998 PDUFA overhead costs were $26 million, or about 10¼ percent. This revised plan assumes this rate remains steady through FY 2002. In reality, recent downsizing of the Office of the Commissioner may reduce this rate, but reductions are likely to be offset by increases in center costs. The overhead costs in this revised plan decrease because fewer staff than originally planned will be hired. The FY 1999 overhead for the drug review process is estimated to be about $26.7 million--down from $28.4 million estimated in the original plan. Over the five year period, this plan reflects about $8.8 million less for PDUFA overhead than the original plan.

As with all PDUFA costs, this overhead has two components: (1) a portion paid from traditional appropriations and (2) a portion paid from fees collected from industry. Under PDUFA I, the portion that must be paid from appropriations was the overhead amount FDA actually spent on this process in 1992, adjusted for cost increases since then. Under PDUFA II, the portion that must be paid from appropriations was the overhead amount FDA actually spent on this process in 1997, adjusted for cost increases since then. The adjusted overhead amount that must come from appropriations in 1999 is $14.6 million.

The difference between the total estimated overhead costs of $26.7 million in FY 1999 and the $14.6 million that must be paid from appropriated funds is $12.1 million. This $12.1 million is the amount of FDA's overhead costs to be paid from fees. Estimates of overhead costs fy fund source over the 5 years of PDUFA II are provided in the chart at the top of the next page.

Projected Drug Review Process Overhead Costs and Source ($000)

Source	1998	1999	2000	2001	2002
S&E Appropriations	$15,165	$14,608	$14,945	$15,302	$15,675
PDUFA Fees	$10,889	$12,052	$12,961	$13,821	$14,512
Total Overhead	**$26,044**	**$26,660**	**$27,906**	**$29,123**	**$30,187**

Use of Overhead Funds

The industry fees supporting overhead will be used in two ways: (1) direct PDUFA support, and (2) indirect support. The direct support funds will pay for specific increases to support the growth of the drug review process. The remainder is indirect support which pays for a portion of the non-center offices that provide agency-level managerial direction and support services for all FDA programs, including PDUFA.

In FY 1998, direct overhead support funded a total of 52 FTE's at a cost of $4.9 million. These FTE's were allocated to Office of the Commissioner components whose work was directly impacted by PDUFA--such as personnel, finance, IT, facilities, contracts, and reviewing waiver requests and orphan designation requests. Over the course of PDUFA II, it is now envisioned that these direct overhead FTE's will increase to 55 by FY 2002. In addition, direct overhead funds will be allotted to the Office of the Chief Information Officer (OCIO) for information management expenses in support of PDUFA II. OCIO will be responsible for developing and maintaining the FDA electronic gateway for the receipt of electronic PDUFA applications submitted to FDA. OCIO will also develop and implement IT standards for PDUFA-related programs and provide oversight for achieving the electronic submission goal. More information about the role and costs associated with OCIO support are provided in the PDUFA II Information Management Five-Year Plan (Attachment 3). A summary of the planned allocation of direct PDUFA overhead over the course of PDUFA II follows.

Projected PDUFA Direct Overhead ($000)

Source	1998	1999	2000	2001	2002
Direct FTE's	52	52	54	55	55
FTE Pay and Support	$4,860	$5,492	$5,670	$5,856	$6,114
IT Support	$438	$691	$1,628	$423	$432
Total	**$5,298**	**$6,183**	**$7,298**	**$6,279**	**$6,546**

FDA Summary Plan

The Agency plan for PDUFA II is a composite of plans developed by CDER, CBER, and ORA. Tables 1-7 on pages 26 and 27 summarize the overall FDA plan. The discussion below summarizes information in each of these tables.

- Table 1 (page 26) shows the $458 million set aside over 5 years to maintain and support the additional staff hired under PDUFA I (referred to as the PDUFA I additive base) discussed in Assumption 1. It also shows the total fee revenues expected annually and the amounts still available for enhancements after the PDUFA I additive base funds have been subtracted from the total estimated fees available--a total of about $220 million over the 5 years.

- Table 2 (page 26) shows the allocation of $224 million over 5 years, by component, planned to meet PDUFA II goals. (This is down from $290 million reflected in the original plan.) The yearly amounts and totals for CDER, CBER, and ORA on the first three lines are from their individual plans. The next three lines show the amounts for: (1) overhead, (2) central accounts, and (3) rental payments to GSA. These are necessary to accommodate the additional staff hired by the centers. The next to last line shows the reserve for contingencies in the later years of the plan (Assumption 8). The total line allocates all the PDUFA funds FDA expects to spend through FY 2002.

- Table 3 (page 26) shows the allocation of this $224 million by expense category. About $39 million will be spent for pay and benefits for a net of 98 additional staff (compared to $95.2 million for 325 additional staff in the original plan). About $87 million is planned for IT enhancements (compared to about $98 million in the original plan). The remainder is planned for other enhancements, operating expenses, overhead, rent, and contingencies. A summary of the change in FTE's planned each year from the PDUFA additive base levels on page 5 are shown below.

PDUFA II Program FTE Changes from the PDUFA I Additive Base

Organization	1998	1999	2000	2001	2002
CDER	+23	+61	+91	+101	+101
CBER	+16	+31	+34	+37	+37
ORA		-10	-40	-40	-40
Total	**+39**	**+82**	**+85**	**+98**	**+98**

- Table 4 (page 26) shows the difference between the projected fee revenues and expenditures each year and the estimated PDUFA carryover balances at the beginning and end of each year. In 1999, FDA will spend about $11 million more than it expects to

collect; in FY 2000 about $7.5 million more. In FY's 2001 and 2002, this plan calls for expenditures of about $6 million and $5.5 million less, respectively, than expected collections. FDA can do this because FY 1999 began with about $67.5 million in PDUFA carryover funds. In FY's 1999 and 2000, when FDA will spend more than it collects, the carryover balance will decrease. In FY 2001 and 2002, when FDA will spend less than it collects, the carryover balance will increase.

While these carryover balances are sizable, FDA must have sufficient carryover funds at the end of each fiscal year in order to begin the following year with no less than 2⅔ months of operating funds (Assumption 3). The table below compares those minimum amounts with planned carryover balances.

Minimum Carryover Balance at the End of Each Fiscal Year and Planned ($000)

Item	1999	2000	2001	2002
Plan for Following Year	$140,363	$143,223	$150,202	$157,712
Minimum Carryover	$31,191	$31,827	$33,378	$35,047
Carryover Balance in Plan	$56,546	$49,044	$55,095	$60,584
Difference -- Minimum vs. Plan	$25,355	$17,217	$21,717	$25,537

Carryover balances at these levels assure adequate funds to begin operations each year and also provide minimal security (1) if there is a substantial shortfall of funds in any one particular year or (2) if the provisions of PDUFA necessitate terminating the program because appropriations are not available at required levels.

- Tables 5 and 6 (page 27) summarize the allocation of the total $681 million that FDA plans to spend over the 5 years of PDUFA II (PDUFA I additive base plus increases) by component and by expense category, respectively. The last column in both tables shows the percent of total PDUFA II funds planned over the next 5 years. By component, CDER will be allocated 56 percent, CBER 20 percent, ORA 4 percent, overhead 9 percent, central accounts 4 percent, rental payments to GSA 3 percent, and contingency reserve 2 percent. By expense category, 56 percent of the total PDUFA II revenues will be dedicated to pay and benefits for staff (compared with 58 percent in the original plan), 13 percent for center/ORA operating costs, 13 percent for IT initiatives, 9 percent for overhead, 4 percent for central accounts, 3 percent for rental payments to GSA, and 2 percent for the contingency reserve.

- Table 7 (page 27) summarizes the total PDUFA FTE's planned each year, showing the number of FTE's paid from the salary and expense appropriations, the number of FTE's paid from fees and considered the PDUFA I additive base, and the number of FTE's added over the course of PDUFA II under this plan.

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FDA Plan Summary Tables--PDUFA II ($000)

Note: Numbers Are Rounded and May Not Add

Table1: PDUFA I Additive Base, and Estimated Funds Available

Item\Year	1998	1999	2000	2001	2002	TOTAL	Percent
Pay and Benefits for Centers/ORA	$61,366	$65,219	$68,480	$71,904	$75,499	$342,469	75%
Base Operating Funds--Centers/ORA	$7,021	$6,726	$6,431	$6,431	$6,431	$33,040	7%
Overhead	$10,889	$10,957	$11,505	$12,080	$12,684	$58,114	13%
Central Accounts	$4,230	$4,642	$4,864	$5,097	$5,342	$24,173	5%
Total--PDUFA I Additive Base	$83,506	$87,544	$91,280	$95,512	$99,956	$457,797	100%
Estimated Fee Receipts	$117,122	$122,527	$132,934	$149,273	$155,691	$677,547	
Available for Enhancements	$33,616	$34,984	$41,654	$53,761	$55,735	$219,750	

Table 2: Funds Planned for Enhancements--by Component

Component\Year	1998	1999	2000	2001	2002	TOTAL	Percent
CDER	$20,100	$27,737	$30,532	$27,356	$27,707	$133,432	60%
CBER	$9,611	$11,262	$9,358	$9,148	$8,993	$48,372	22%
ORA	$903	($140)	($1,446)	($1,122)	($2,114)	($3,920)	-2%
Overhead	$0	$1,096	$1,456	$1,741	$1,828	$6,120	3%
Central Accounts	$0	$574	$613	$728	$750	$2,664	1%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,083	$23,014	10%
Contingency Reserve	$0	$0	$3,000	$4,000	$7,000	$14,000	6%
Total	$30,614	$45,956	$49,155	$47,711	$50,246	$223,683	100%

Table 3: Funds Planned for Enhancements--by Expense Category

Expense Category\Year	1998	1999	2000	2001	2002	Total	Percent
Pay and Benefits for Centers/ORA	$2,263	$6,521	$8,668	$10,362	$10,880	$38,693	17%
Support Costs for Personnel	$1,943	$2,097	$2,279	$2,271	$2,072	$10,660	5%
Process Enhancements	$5,246	$10,137	$8,890	$9,227	$8,207	$41,707	19%
IT	$21,163	$20,104	$18,607	$13,523	$13,427	$86,824	39%
Subtotal to Centers	$30,614	$38,859	$38,443	$35,382	$34,586	$177,884	80%
Overhead	$0	$1,096	$1,456	$1,741	$1,828	$6,120	3%
Central Accounts	$0	$574	$613	$728	$750	$2,664	1%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,083	$23,014	10%
Contingency Reserve	$0	$0	$3,000	$4,000	$7,000	$14,000	6%
Total	$30,614	$45,956	$49,155	$47,711	$50,246	$223,683	100%

4. Difference Between Plans and Available Funds, with Year-End Carry-Over Balances

Category\Year	1998	1999	2000	2001	2002
Difference Between Plan & Available		($10,973)	($7,501)	$6,051	$5,489
Est. Carry-Over Balance-Year Beginning		$67,518	$56,546	$49,044	$55,095
Est. Carry-Over Balance-Year End	$67,518	$56,546	$49,044	$55,095	$60,584

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FDA Plan Summary Tables--PDUFA II ($000)

Note: Numbers Are Rounded and May Not Add

Table 5: FDA Summary of all PDUFA Additive Resources--by Component

Component\Year	1998	1999	2000	2001	2002	TOTAL	Percent
CDER	$64,199	$76,031	$81,052	$80,215	$83,020	$384,517	56%
CBER	$27,684	$28,381	$26,947	$27,542	$28,231	$138,785	20%
ORA	$7,118	$6,393	$5,355	$5,961	$5,265	$30,092	4%
Overhead	$10,889	$12,052	$12,961	$13,821	$14,512	$64,235	9%
Central Accounts	$4,230	$5,216	$5,476	$5,825	$6,091	$26,838	4%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,083	$23,014	3%
Contingency Reserve	$0	$0	$3,000	$4,000	$7,000	$14,000	2%
Total	$114,120	$133,500	$140,435	$143,223	$150,202	$681,480	100%

Table 6: FDA Summary of all PDUFA Additive Resources--by Expense Category

Expense Category\Year	1998	1999	2000	2001	2002	TOTAL	Percent
Pay and Benefits for Centers/ORA	$63,629	$71,741	$77,148	$82,266	$86,379	$381,163	56%
Operating Funds--Excluding IT	$14,210	$18,960	$17,600	$17,929	$16,710	$85,407	13%
Information Technology	$21,163	$20,104	$18,607	$13,523	$13,427	$86,824	13%
Overhead	$10,889	$12,052	$12,961	$13,821	$14,512	$64,235	9%
Central Accounts	$4,230	$5,216	$5,476	$5,825	$6,091	$26,838	4%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,083	$23,014	3%
Contingency Reserve	$0	$0	$3,000	$4,000	$7,000	$14,000	2%
Total	$114,120	$133,500	$140,435	$143,223	$150,202	$681,480	100%

Table 7: FDA Summary of all PDUFA FTE's for CDER, CBER, and ORA

Expense Category\Year	1998	1999	2000	2001	2002
Base FTE's Paid from Appropriations	1,147	1,147	1,147	1,147	1,147
PDUFA I Additive Base FTE's	659	659	659	659	659
FTE's Added for PDUFA II	39	82	85	98	98
Total	$1,845	$1,888	$1,891	$1,904	$1,904

Annual Reassessments

As initially envisioned, this plan will continue to be revised each year based on the latest information available. This plan is intended to let the centers and ORA know the amounts to expect each year. This early information should facilitate the work required to meet the PDUFA II goals. Actual workload and revenues must be monitored closely.

The plan is meant to be a dynamic framework for the investments FDA must make. It will be updated in the second quarter of each fiscal year. That update will take into account the actual accomplishments, workload, revenues, and expenses of the previous fiscal year and the planned accomplishments, workload, revenues and fees to be charged in the current year, as set out in the annual *Federal Register* fee adjustment notice.

If revenues are expected to be at levels lower than the assumptions of this plan, or if actual PDUFA expenditures by CDER, CBER or ORA in the previous year are significantly less than the amounts allocated, then cutbacks in hiring and other expenses will be required as was the case in this 1999 revision. On the other hand, if PDUFA revenues exceed planned amounts because workload increases at a rate greater than planned, the additional revenues will need to be allocated to cope with these increases. Also, if unforeseen contingencies do not necessitate using the contingency reserve, it will be allocated by the end of the second quarter of each year.

During PDUFA II, FDA's Office of Management and Systems will look closely at PDUFA costs and workload. If that assessment indicates that PDUFA workload is out of kilter with the distribution of resources in this plan, then adjustments will be made.

Because all funds FDA expects to collect have been planned, adjustments made by the centers and ORA each year will generally be within the total amounts already planned for each fiscal year. For example, if an unplanned IT item becomes a high priority, then cutbacks will have to be made in other components of that organization's plan (such as other IT items, hiring, or operating support) in order to fund that need.